

# Participant Information Sheet

## Questionnaire

Exploring the food intake and access for pregnant women in the UK  
Principal Investigator: Nicola Heslehurst, Newcastle University

We would like to invite you to take part in a research study. Before you decide if you want to take part it is important that you understand what it will involve. Please take the time to read this document and discuss it with friends and family (if you want to). If there is anything you are not sure about or you would like to discuss with a member of the research team, please email, call, text or WhatsApp us on:

Alternatively, you can contact your local NHS maternity research team at

This leaflet is split into two parts:

- Part 1: The Basics - tells you about the study and what would happen if you decided to take part
- Part 2: The Finer Detail - gives more details about the conduct of the research

Additionally, a brief video outlining the basic information contained in this leaflet can be found by scanning the QR code or visiting our website  
<https://sphr.nihr.ac.uk/food-pregnancy-and-me/>



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## Part One: The Basics

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### 1. Why is this study needed?

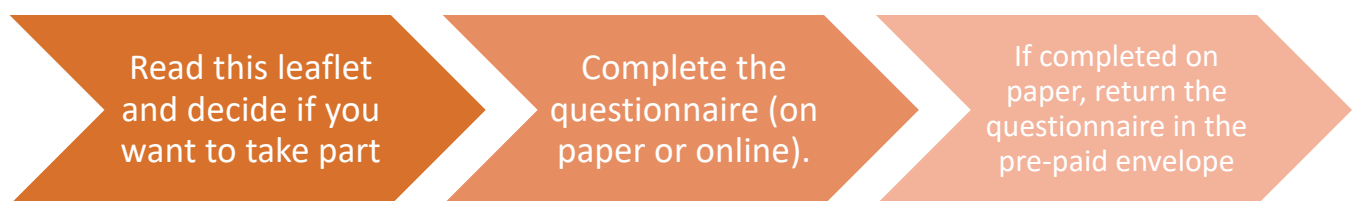
In the UK, we don't have much information about what food is eaten and how it is accessed during pregnancy. We would like to find out more about the food you eat, how you access food and your health and wellbeing during your pregnancy. This information will help us to better understand whether pregnant people need more support to access the food and nutrients they need.

### 2. Why am I being asked to take part in this study?

- You are pregnant and in your third trimester (29-40 weeks gestation)
- You are having care at either Queen Elizabeth Hospital (QEH) Gateshead or University Hospital Coventry and Warwickshire (UHCW)

### 3. What happens if I take part?

#### What do I need to do?



We would like you to complete the questionnaire in this pack. There are many things that affect what we eat and how we access food, lots of which are not in our control. For this research to find out what will help pregnant people who are struggling in the future, it is important that you answer the questionnaire honestly.

In this research study, we will use information from you and your maternity records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

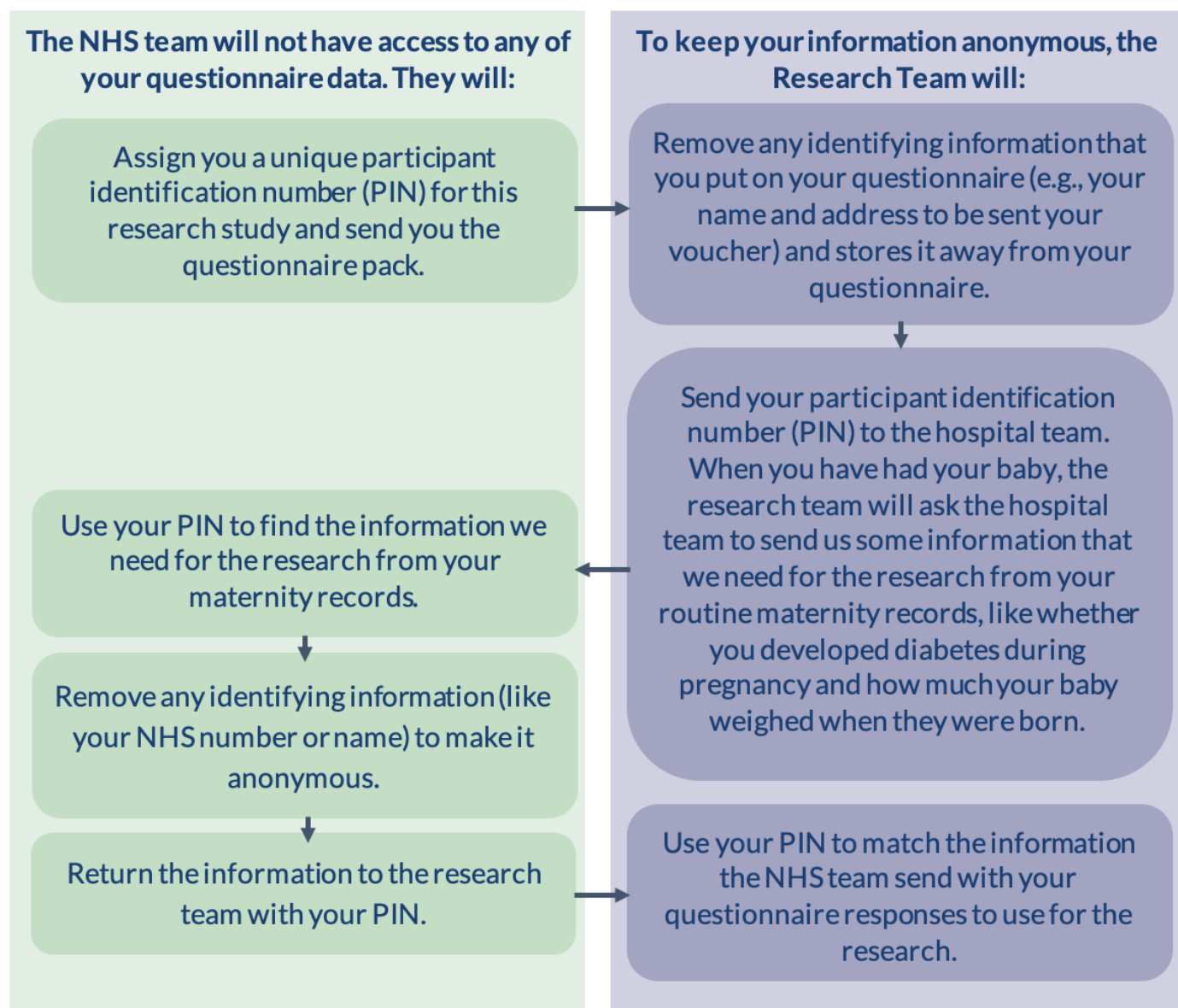
In exceptional circumstances, the researcher may need to break confidentiality if they think you are a serious risk of harm or danger to yourself or others. In these cases, we will advise the research midwife at your local maternity unit of the unique participant information number (PIN) on the questionnaire and a brief description of the reason (e.g., questionnaire

score suggests maternal depression). A midwife will then contact you, however they will not have access to your questionnaire data.

We would like to make sure that anyone who would like to answer our questionnaire is able to. If you would like the questionnaire in a language other than English or have a member of the research team read the questionnaire to you over the phone, please let us know and we will arrange this.

### Who sees my data and what happens next?

The flow chart on the next page shows how your information will be handled. At the end of the study, we will save some of the data in case we need to check it. We will make sure no-one can work out who you are from the reports we write. More information on what will be collected, who will access it, and how it will be stored can be found in The Finer Detail section of this leaflet. We would like around 600 people to send back a questionnaire.



If you are a patient at a participating hospital for your antenatal care, but live out-of-area (i.e., care at UHCW/QEH but live outside of Coventry/Gateshead), the NHS team may need to contact your local Trust to access the information needed for the study from your maternity record.

#### 4. Are there any benefits or risks for me in joining the study?

There is no immediate benefit to you if you take part. However, **you will receive a £20 voucher to thank you** for taking the time to complete and return the questionnaire. You will need to complete the whole questionnaire to receive the voucher. If you miss any questions, the research team may contact you directly using the contact details you provide on the questionnaire, if you give permission for us to do so. There may be benefits to future pregnant people if this research helps to find out what support pregnant people need to access food. There are no anticipated risks to taking part in this study.

#### 5. Do I have to take part?

No, it is completely up to you. If you decide not to take part, simply do not respond to this questionnaire. Your decision has no impact on the care you will receive from your local maternity care team. If you decide to take part and then change your mind, you are free to stop taking part at any time, without giving a reason, but we will keep the information about you that we already have. You can stop taking part by contacting us using the details at the end of this leaflet. As we don't hold your personal details, you will need the PIN number on page 1 of this document to tell us who you are.

#### 6. The Optional Extra Study

We would also like to talk to around 40 people (20 each from Coventry and Gateshead maternity units) in more detail about their experiences accessing food during their pregnancy. This is called a research interview. **Participants in these interviews will receive an additional £25 voucher as a thank you for their time.** If you would be happy to talk to us, please provide your contact details on page 2 of the questionnaire (or when prompted online). Due to the small number of people needed for the optional part of the study, you may or may not be approached by the research team about this optional extra.

If you are approached: You will be given another information sheet with more detail about the extra study, and you will be able to discuss the optional study with the research team before deciding whether you want to take part. You will be asked to sign a consent form if you decide to take part in the research interview.

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## Part Two: the finer detail

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### 7. Who will be able to access and use my information?

We will use information from you and your medical records as part of this study. This will include information from your medical record as described on page 7. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. People will use this information to do the research or to check your records to make sure that the research is being done properly. Your maternity care team may send reminders to complete the questionnaire through their normal contact route (e.g., text message or maternity app). Your contact details will only be seen by the research team if you provide them and will only be used for the reasons you give permission for on page 2 of the questionnaire. For example, if you miss any questions, the research team may contact you to complete them using the contact details you provide on the questionnaire if you give permission for us to do so. We will keep all information about you safe and secure.

Newcastle University, based in the UK, is the sponsor for this study and will act as the data controller. This means that Newcastle University are responsible for looking after your information and using it properly. All the information you provide will be kept confidential and stored securely at Newcastle University for ten years after the study has finished.

Individuals from Newcastle University and regulatory organisations may look at your medical and research records to check the accuracy of the research (known as an audit). If an audit happens, regulatory authorities will be provided with the document that links your PIN with your NHS number to check that we have carried out the research correctly. No other party will be given any individual's information, and we will not allow access to the police, social services, relatives, or lawyers, unless forced to do so by the courts. **We will always protect your privacy.**

If you take part in the research study, information provided by you may be shared with researchers running other research studies at Newcastle University and in other organisations. These organisations may be universities NHS or Local Authority organisations. Your information will only be used by organisations and researchers to conduct research.

### University stored data:

Your stored questionnaire data will only use your PIN and no other identifying details. University researchers working with your data will not know who you are.

If you return the paper questionnaire and choose to give us your contact details on page 2, we will remove this page and store it separately. If you return your questionnaire online, your identifying data will also be removed and stored separately from the questionnaire data. If you gave your contact details to take part in the optional extra study (see Section 6) and live in Coventry, your details may be securely transferred to the University of Birmingham for the research team there to contact you.

All study data will be stored in a restricted-access study database. The study data will be linked to your PIN, but your personal details (e.g., name, date of birth, address) will never appear in this database. Your anonymous information will be available only to researchers who have scientific and ethical approval to access your data and where access is relevant to taking part in this research.

### **NHS stored data**

The NHS researchers (e.g., research midwives) working at your maternity unit allocated you a PIN that is unique to you when they sent you this questionnaire pack.

They have an electronic document linking your PIN to your NHS number, which is stored in a password protected secure NHS server and only accessible to the NHS researchers (e.g., the research midwife). This document will be stored for ten years after the study ends and then destroyed.

The document will only be used to get relevant health information from your maternity records needed for this research (detailed on page 7). Your health information will be sent securely to the University research team and will only include your PIN and no other identifying details. Your PIN will be used by the University research team to link your anonymised health information with your questionnaire answers.

You are free to stop taking part at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. Research could go wrong if data is removed or changed. To safeguard your rights, the minimum personally-identifiable information will be used. You can find out more about how Newcastle University uses your information at:

<https://www.ncl.ac.uk/data.protection/dataprotectionpolicy/privacynotice/> and/or by contacting Newcastle University's Data Protection Officer (Maureen Wilkinson, [rec-man@ncl.ac.uk](mailto:rec-man@ncl.ac.uk)).



## 8. How will my data be stored?

Any paper documents will be stored in a locked fire-resistant cabinet at Newcastle University and only accessed by the research team. Online questionnaire data will be collected via an online survey software which is ISO 27001 and GDPR compliant. To allow us to complete the analysis, all anonymised data will be transferred to a secure server at Newcastle University and stored in accordance with GDPR and the Data Protection Act 2018.

## 9. How will I give consent?

Completing the questionnaire and returning it to us will act as consent to take part in the study. By returning a completed questionnaire, you are confirming that you understand that:

1. Your participation is voluntary, and you are free to stop taking part at any time, without giving a reason, and without your medical care or legal rights being affected.
2. You agree to the research team at the NHS sites storing your NHS number linked to your PIN.
3. Your anonymised data will be held securely on a Newcastle University server in line with current data protection regulations, and that the data will not be used for any other purposes than described in this document.
4. The NHS research team will access, anonymise, and securely send the University research team the following information from routine maternity records:
  - your age, ethnic group, postcode
  - how many previous pregnancies you have had
  - your weight, height, and body mass index
  - any relevant medical history (e.g., depression, previous pregnancy health such as low birth weight)
  - any alcohol or drug use
  - Whooley score (depression screening)
  - diabetes, pre-eclampsia, or pregnancy-induced hypertension in this pregnancy
  - whether you were induced, how and when you delivered your baby, and how long you stayed in the maternity unit
  - your baby's sex, birthweight, and gestational age (the number of weeks when they were born)
  - whether your baby was admitted to a special care baby unit and, if so, how long for
  - your baby's Apgar score (a newborn health check)
  - breastfeeding information

## 10. What will happen to the results of the research study?

The researchers conducting the study are required to publish the results of the research so that people can benefit from it. The results will also be made available to participants and anyone else who might be interested at

<https://sphr.nihr.ac.uk/research/>. The research team may also present the results at

local, national, and international conferences. **We will write our reports and presentations in a way that no-one can work out that you took part in the study.**

**11. Who has organised and funded this study?**

This study has been funded by the National Institute for Health and Social Care Research, School for Public Health Research. It is being organised by researchers based at Newcastle University, University of Birmingham, Teesside University and University of Lancaster. We are working with Coventry and Gateshead NHS Maternity Services.

**12. Who has approved this study?**

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This project has been reviewed and approved by the Newcastle and North Tyneside research ethics committee.

**13. Who do I contact if I have concerns?**

If you have any concerns or complaints about anything to do with this study, then you can call, text or WhatsApp us on: 07440 486843 Mon to Fri: 10:00-16:00 or email us at: [FPandMe@newcastle.ac.uk](mailto:FPandMe@newcastle.ac.uk)

Alternatively, if you would like to write to the person in charge, please send your letter to: Prof. Nicola Heslehurst, Food, Pregnancy and Me, Baddiley-Clark Building, Richardson Road, Newcastle University, Newcastle upon Tyne, NE2 4AX.

We will reply to your letter promptly in writing, unless you enclose your telephone number and wish to discuss your concerns with us.

- **Thank you for taking the time to read this information.**
- **If you would like to take part in this research, please either:**
  - **Complete the questionnaire and post it back to us using the paid addressed envelope provided.**
  - **Or complete the questionnaire online by scanning the QR code or visiting:**

[tinyurl.com/foodpregnancy](https://tinyurl.com/foodpregnancy)

